



## QUESTIONS AND ANSWERS FOR SECURITY PRINTERS (Revised 3/22/05)

### Q What is an *approved* “security printer”?

A A *security printer* is a printing company that has applied to and been *approved* by the Board of Pharmacy and the Department of Justice to produce the new tamper-resistant security prescription forms for use by authorized prescribers. If a security printer is not listed on the Board of Pharmacy website at [http://www.pharmacy.ca.gov/consumers/security\\_printer\\_list.htm](http://www.pharmacy.ca.gov/consumers/security_printer_list.htm), it is **not** approved, and cannot legally print the new security prescription forms.

### Q What do I need to qualify to become an approved security printer?

A The security printer must have a secure facility, adequate staffing, and policies and procedures that meet or exceed requirements of Health and Safety Code section 11161.5 as well as the security printing knowledge and the equipment necessary to produce tamper-resistant security prescription forms including all of the security features required in section 11162.1 et seq. The board would prefer that all approved security printers have the capability to apply all of the security features in-house; however, the board is allowing approved printers to purchase a base stock paper (unformatted) that includes the chemical void protection and/or latent repetitive void protection only.

### Q How does a print company apply to the Board of Pharmacy for approval to produce the new controlled substance prescription forms for use by authorized prescribers?

A Visit the Board of Pharmacy security printer website at [www.pharmacy.ca.gov/consumers/security\\_printer.htm](http://www.pharmacy.ca.gov/consumers/security_printer.htm) to download an “*Application and Instructions*”, as well as, the “*Guidelines for Security Printer Policies and Procedures.*” The laws pertaining to the approval process and prescription form requirements can be found under [Health and Safety Code sections 11161.5 and 11162.1 et seq.](#) The new prescription form requirements and other changes to prescribing and dispensing laws are a result of [Senate Bill 151 \(Burton, Statutes of 2003\)](#). Other frequently asked questions and answers that pertain to SB 151 changes can be found under the “[prescribing and dispensing](#)” link on our website at [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov).

In addition to completing the application, all owners, corporate officers, and general managing partners of the business or corporation must submit fingerprints for a thorough criminal background check through the Department of Justice and Federal Bureau of Investigation. Applicants must also submit policies and procedures that meet or exceed the requirements outlined in the aforementioned Health and Safety Codes.

Submit your completed application, along with copies of Live Scan forms or fingerprint cards (out-of-state applicants), and the required policies and procedures to the Board of Pharmacy 400 R Street, Suite 4070, Sacramento, CA 95814. There is no fee to apply; however, if you are submitting fingerprint cards for any of the owners, corporate officers, or general managing

partners, you must submit \$65 for each to cover the costs associated with the criminal background checks. Please combine amounts whenever possible. The board accepts checks or money orders made payable to the Board of Pharmacy. Please do not send cash. A similar fee amount will be charged at the Live Scan site for those submitting fingerprints via Live Scan. The fees for Live Scan vary from site to site. A list of Live Scan sites can be found at <http://ag.ca.gov/fingerprints/publications/contact.pdf>. The board recommends that you call Live Scan sites in advance to confirm fees, acceptable methods of payment, and hours of operation. An appointment may also be required. If you have any questions, please email [security\\_printer@dca.ca.gov](mailto:security_printer@dca.ca.gov). The approval process can take 45 days or more.

**Q** What is required to be included in the security printer's policies and procedures?

- A** As outlined in Health and Safety Code section 11161.5 et seq., to qualify for approval as a designated "security printer" you must submit the following with your application:
- ♦ Policy relating to your ability to produce controlled substance prescription forms that meet or exceed requirements outlined in section 11162.1 and adequate policies and procedures relating to the production and distribution of controlled substance prescription forms;
  - ♦ Policy and procedures for verifying the identity of the prescriber ordering the controlled substance prescription forms, and their authority to prescribe controlled substances;
  - ♦ Policy and procedures for verifying delivery of the controlled substance prescription forms to the prescriber; and
  - ♦ Policy and procedures for the maintenance of ordering and delivery records in a readily retrievable format for three years.

Applications submitted without policies and procedures cannot be processed. Please review and follow the "[Guidelines for Security Printer Policies and Procedures](#)" available on our website, when writing your policies and procedures. Policies and procedures must meet or exceed all of the requirements pursuant to [Health and Safety Code sections 11161.5 and 11162.1 et seq.](#) Printers will find the various questions and answers available on our website helpful also.

**Q** My security printing business is located out-of-state or out-of-the country; can I apply to become an approved security printer?

- A** Yes. The board encourages any printer that meets or exceeds the requirements outlined in Health and Safety Code section 11161.5 & 11162.1 et seq., to submit their application to the board for review. If the business is a corporation, the business must register with the California Secretary of State's office in order to do business with California prescribers. Please visit the Secretary of State's website at <http://www.ss.ca.gov/business/business.htm> for more information and forms necessary for registration. You may submit both your application to the Board of Pharmacy and registration to the Secretary of State simultaneously; simply note that you are in the process of registering with the Secretary of State in your cover letter to the board. Please send a copy of the registration, once received, to the Board of Pharmacy. Applicants from outside the U.S. will also be required to submit fingerprints through the international organization, Interpol. Contact the Department of Justice at 916-319-9062 for information about submitting fingerprints through Interpol.

**Q** Can I use distributors or dealers to market and/or take orders for our prescription forms?

**A** Yes. The board approves the security printer; therefore, the printer is responsible for producing the prescription forms, verifying prescribers' license and DEA registrations, and all record keeping. Printers may choose to use distributors to market their prescription products and/or accept orders from the prescribers. Printers applying to become an approved printer must include in their policies and procedures submitted with their application, the details surrounding the distributors' role and responsibilities. Currently approved printers that later choose to use distributors must update their policies and procedures and submit a revised copy to the Board of Pharmacy immediately.

The board strongly recommends approved printers enter into a formal agreement with their distributors/dealers, which details responsibilities, expectations, record requirements, and limitations on advertising, etc. In addition, the board recommends that the approved printer perform all license and DEA verification, as the approved printer is responsible for ensuring prescription forms are provided to authorized and currently licensed prescribers only. No distributor or dealer may receive delivery for or forward prescription forms to prescribers. Approved printers must ship prescription orders directly to the prescriber – no exceptions. All distributor/dealer advertising must identify that they are an authorized distributor for [name of approved security printer].

The Board of Pharmacy no longer posts distributors on its "[List of Approved Security Printers](#)" web page. Approved printers that choose to use distributors must develop and continuously maintain their own web page that lists all of their authorized distributors with pertinent contact information. Please be prepared to provide the website address to the Board of Pharmacy upon approval of your application. A hot link will be included below your contact information on the board's website that reads, "[Click here to order from an authorized distributor near you](#)".

**Important note:** Approved printers that fail to continuously maintain their distributor website may be grounds for the board to revoke its approval.

**Q** What is an "agent for service of process" that is required to be included on the *Security Printer Application for Approval to Produce Controlled Substance Prescription Forms*?

**A** This information should match the agent for service of process filed with the California Secretary of State's Office. Domestic (California) and foreign (out-of-state or out-of-country) owned corporations are required to register with the Secretary of State to do business with California residents and businesses. As part of that process, the corporation must designate an agent for service of process in California. An agent for service of process, as defined by the California Secretary of State, is an individual (or another corporation) designated by a corporation to accept service of process if the corporation is sued. California residency is the only requirement for an individual to be named as an agent for service of process. A corporation named as an agent for service of process must have on file with the California Secretary of State, a certificate pursuant to Section 1505 of the California Corporations Code. **Note:** A corporation cannot act as its own agent. Approval from a proposed agent should be obtained prior to designation.

**Q** My corporation is large, how many principle corporate officers are required to submit fingerprints and complete the ownership page of the security printer application?

**A** Generally, the top three to five corporate officers; such as the president, vice president, chief financial officer, secretary, executive officer, any other officer of the corporation or person who performs policymaking functions for the day-to-day operations of the corporation.

## **Prescriber License and DEA Registration Verification**

**Q** How and where do I verify a prescriber's state license number?

**A** The approved security printer must verify that the state license of every prescriber preprinted on the prescription form is current, active, and has no prescribing restrictions. California state practitioner licenses can be verified online. Go to [www.dca.ca.gov](http://www.dca.ca.gov) and click on the *License and Complaint History* link. From the menu, choose the prescriber's license type (for example; for a physician go to the Medical Board of California and choose physicians and surgeons or for a dentist go to the Dental Board of California and choose dental license, etc). **Note:** for nurse practitioners and certified nurse midwives please obtain his or her state furnishing number (NPF). Enter the state license number or furnishing number following the instructions. Look to make sure the license says clear, renewed or active. Then also check to see if there is anything listed under public disclosure, for example, probation or suspension. Scroll down to read a description of the conditions of probation or suspension, if applicable. If there are any limitations on prescribing, dispensing, or administering controlled substances, it should describe the restriction but it may not always provide this information. Read the limitation carefully as the restriction may be only for Schedule II drugs or for a specific drug. In that case, the prescriber can still order the controlled substance security prescription forms to use for other controlled substance prescriptions.

Please contact the applicable licensing board (below) to obtain authorization if the disclosure does not specifically address prescribing privileges or anytime you have a question or concern about a prescriber's license or furnishing number and/or their authority to write controlled substance prescriptions. Printers may not print controlled substance prescription forms for any unauthorized prescriber. The board recommends printing a copy for the file.

### ***CA State Licensing Board Phone Numbers for License Verification Issues and Questions***

Dentists	Dental Board of California	916-263-2300 ext. 2328
Nurse Practitioners and Certified Nurse Midwives	Board of Registered Nursing	916-324-2715 ask for nursing education consultant
Optometrists	Board of Optometry	916-445-8663
Osteopathic Physicians	Osteopathic Medical Board	916-263-3100
Pharmacists	Board of Pharmacy	916-445-5014 ext. 4019
Physician Assistants	Physician Assistant Committee	916-263-2670
Physicians and Surgeons	Medical Board of California	916-263-2499 or 916-263-2382
Podiatrists	Board of Podiatric Medicine	916-263-2647
Veterinarians	Veterinary Medical Board	916-263-2610 or 916-263-2617

**Q How do I verify that the prescriber has the authority to write a controlled substance prescription?**

**A** The security printer must obtain a copy of the DEA registration for every prescriber preprinted on the prescription form. A copy must be obtained with every order, even repeat orders. As an alternative to obtaining a copy from the prescriber, the security printer can purchase a monthly subscription of the DEA registration database and print a copy from the database or save an electronic record. In either case, the security printer must check that the DEA registration is not expired, the prescriber is authorized to write a controlled substance prescription (Schedule 2, 2N, 3, 3N, 4 and/or 5), that the name on the registration matches what will be printed on the prescription form, and make a record that these items have been verified.

**Q Can an out-of-state prescriber order controlled substance prescription forms to use when treating their California patients?**

**A** Yes. The approved printer is required to contact the prescriber's licensing board in the state in which he or she is licensed to verify the license is valid and there are no restrictions.

## **Prescription Form Requirements**

**Q Where do I find the controlled substance prescription form requirements?**

**A** [Health and Safety Code section 11162.1 et seq.](#) requires several specific security features to be included on the controlled substance prescription form, as well as, specific formatting, preprinted prescriber information, and multiple form styles required. Form samples and additional information can be found on our website at [http://www.pharmacy.ca.gov/consumers/security\\_printer.htm](http://www.pharmacy.ca.gov/consumers/security_printer.htm). Questions can be emailed to [Security\\_Printer@dca.ca.gov](mailto:Security_Printer@dca.ca.gov).

The board cannot recommend paper or thermochromic ink companies. The board does not have the authority to “approve” your prescription forms nor can it provide law interpretations. The board strongly recommends that printers seek legal assistance to ensure full compliance with all relevant laws and regulations.

**Q Can I order blank stock paper with all or most of the security features already applied?**

**A** No. In order to be approved, security printers must have the experience and equipment needed to apply the required security features pursuant to Health and Safety Code section 11162.1 et seq. at their facility. The board is allowing approved printers to order a blank stock paper that includes the latent repetitive void and/or the chemical void protections — but nothing more. The board cannot recommend paper or ink suppliers.

**Q** What does “an area of opaque writing so that the writing disappears if the prescription is lightened” mean pursuant to Health and Safety Code section 11162.1, subdivision (a)(5)?

**A** This requirement can be fulfilled in either of two ways. The most common is sometimes referred to as reverse printing, which is a colored background with an opaque symbol (e.g., an Rx symbol) that disappears if the prescription is lightened repeatedly on a copier. Another way is microprinting, which is very small text that appears to be a line but can be seen when magnified. The microprinted text becomes a solid line if the prescription is copied.

**Q** What does “a feature printed in thermochromic ink” mean as identified in Health and Safety Code section 11162.1, subdivision (a)(4)?

**A** Thermochromic ink is a special ink that changes color or disappears temporarily when exposed to heat. The ink will temporarily change color or disappear when rubbed briskly or by blowing hot breath over the feature. The ink will slowly return to its original color as the feature cools. The feature can be of any design of the approved security printer’s choice. Examples include, but are not limited to: the “Rx” symbol or similar logo, the text that describes the feature, a thumbprint that disappears to reveal “valid” underneath, etc. The required description of security features should identify what feature is printed in thermochromic ink.

**Q** Health and Safety Code section 11162.1, subdivision (a), paragraph (6), requires a description of the security features be included on each prescription form, what does this mean?

**A** The law is not specific; however, the board encourages all approved security printers to include a description of all security features in a manner that will assist a busy pharmacist to quickly check the form’s validity. For example:

Poor	Thermochromic ink feature.
Better	Rx symbol changes color with hot breath or when rubbed briskly.
Poor	Latent repetitive void protection.
Better	Void pattern appears across face of form when copied or faxed.
Poor	Chemical void protection.
Better	Chemical alteration will produce stained appearance.

Security feature descriptions can be on the back of the form, in warning bands on the front of the form, or a combination of both.

**Q** Is there a specific size or color requirement for the new tamper-resistant security prescription forms?

**A** No. Form design and color is the approved security printer’s choice as long as all of the security features and preprinted prescriber requirements pursuant to Health and Safety Code section 11162.1 et seq., are met or exceeded. Many printers have developed several different versions of the new controlled substance security prescription forms. For example; custom institution forms, duplicate/multiple copy forms, all-in-one hospital release forms that



incorporate a security prescription form, forms designed to print out on laser and/or dot matrix printers, medical group forms listing all prescribers in a group with checkboxes, etc.

**Q** Is there more than one style of prescription form that an approved security printer is required to provide?

**A** Yes, section 11162.1 of the Health and Safety Code describes essentially three versions of the new controlled substance security prescription form. Under subdivision (a), paragraph (8), prescriptions must include either a statement that says, "Prescription is void if more than one controlled substance prescription is written per blank" **OR** a statement that says, "Void if the number of drugs prescribed is not noted" together with a space provided for the prescriber to specify the number of drugs prescribed. In essence, this means a form to write one controlled substance prescription per blank or a form that allows multiple prescriptions per blank. When designing the form for multiple drug prescriptions, the board recommends sectioning the form for each drug and including quantity check off boxes, refill, and "order not to substitute" choices for each drug section. However, this is not required by law. The third version of the form is an "institution" style form as described under subsection (c). See "Forms for Licensed Health Care Facilities" below for more information and the requirements associated with this style of form.

**Q** Can I offer duplicate or triplicate controlled substance security prescription forms if my customers ask for it?

**A** Yes, as long as the actual prescription (top copy) includes all of the security features detailed in Health and Safety Code section 11162.1. The board recommends that the copies indicate "not a valid prescription," or "nonnegotiable," or something similar to ensure that the copies cannot be confused as the original.

**Q** Can a pharmaceutical manufacturer or other entity place an order for prescription pads on behalf of a prescriber and pay for it? If so, can they be listed on the prescription form for advertising purposes?

**A** Policies for payment for the new controlled substance prescription forms are matters to be recommended by the approved security printer. The forms cannot be shipped to the third party that is paying for the order. The prescription forms must be delivered to the prescriber's address and a signature upon delivery is required. Advertising information printed on the form and/or within a pad of forms, is not objectionable to the board.

**Q** Can controlled substance medications be preprinted onto a controlled substance prescription form so that a prescriber can simply check a box next to the desired controlled substance drug name, strength, and quantity that is preprinted on the form?

**A** No, California Code of Regulations section 1717.3(a) prohibits preprinted, multiple check off prescription blanks for any controlled substance.

## Preprinted Prescriber Information

### ❶ What information about the prescriber must be preprinted on the controlled substance prescription blank?

**A** Controlled substance security prescription forms must be preprinted with the prescriber's name, category of licensure (e.g., MD, DDS, etc.), state license number (or nurse practitioner's furnishing number), and federal controlled substance registration number (DEA number). The approved printer must print the prescriber's name as it appears on the DEA registration. In addition, the prescriber's address and phone number is required to be on the form to be a valid prescription; therefore, the board recommends this information be preprinted as well. However, locum tenens physicians or other physicians that substitute at various facilities may opt to not preprint the address and phone number, but instead stamp or handwrite this information at the time the prescription is written.

### ❷ Can the prescriber name printed on the prescription form differ from the name on the DEA registration; for example, last name changed due to marriage or divorce, or the prescriber wants to abbreviate the name from David to Dave, etc?

**A** No. The prescriber name must match exactly to the name listed on the DEA registration and state license. If the prescriber has recently had a name change due to marriage or divorce, she is required to submit a name change with the DEA and the state licensing board immediately. Printers can print the prescription forms as long as the prescriber provides copies of the name change paperwork submitted to the DEA and state licensing board. However, prescribers cannot use the new prescription forms until they receive their new DEA registration and state license.

### ❸ If a prescriber has several offices, can he or she order the new controlled substance prescription forms preprinted with all of the addresses listed?

**A** Yes, multiple addresses for one prescriber may be listed on the prescription form but should include check off boxes next to each address listed so that the prescriber can checkmark the location where the patient was seen.

### ❹ Can the new controlled substance prescription forms be preprinted with more than one prescriber in a group practice or clinic setting?

**A** Yes, however, the forms should include a check box next to each prescriber's name, category of licensure, state license number, and DEA number so that prescribing physician can checkmark the applicable box when writing the prescription. The number of prescribers that can be listed on the prescription form is limited only by the approved printer's form design.

**Note:** "institution" forms (explained in section *Prescription Forms for Licensed Health Care Facilities* below) are not an option for group practices or any outpatient facilities such as, clinics or surgery centers.



**Q** Is a federal controlled substance registration number the same thing as a DEA Registration number?

**A** Yes

**Q** What does the “category of licensure” mean in the preprinted prescriber requirements?

**A** The category of licensure is the practitioner’s license category or degree; for example, the MD (medical doctor), DDS (doctor of dental surgery), OD (doctor of osteopathy, PA (physician assistant), etc., identified as initials that follow the practitioners printed name.

**Q** Can a nurse practitioner, certified nurse midwife, or physician assistant stamp or handwrite their name, category of licensure, DEA registration number, and license number on their supervising physician’s preprinted security prescription pad to write a controlled substance prescription?

**A** No. The law requires the prescriber to be preprinted on the new controlled substance prescription forms; therefore, the nurse practitioner, certified nurse midwife, or physician assistant signing the prescription must have his or her name, category of licensure, license number (furnishing number for nurse practitioners and certified nurse midwives), and DEA registration number preprinted on the controlled substance prescription form by a board-approved security printer. (H & S 11162.1 (a) (9))

**Q** Is a supervising physician’s information required to also be printed on a nurse practitioner’s or certified nurse midwife’s preprinted controlled substance prescription form?

**A** No, the supervising physician’s information is no longer required to be on the nurse practitioner’s or certified nurse midwife’s preprinted controlled substance prescription form. The nurse practitioner or certified nurse midwife’s furnishing number (NPF), DEA registration number, name, and category of licensure must be preprinted on the form. (B & P 2836.1 (f) & (i))

**Q** Is a supervising physician required to be printed on a physician assistant’s preprinted controlled substance prescription form?

**A** Yes. The law requires that a physician assistant authorized to write controlled substance drug orders pursuant to authority granted to them by their supervising physician and DEA registration, must have their supervising physician’s name, DEA registration number, address, and telephone number preprinted on the physician assistant’s preprinted controlled substance prescription form. (Business and Professions Code section 3502.1 [b] & [d] and Health and Safety Code section 11162.1[a][9])

**Q** Can an approved security printer offer controlled substance prescription forms for laser and/or dot matrix printers?

**A** Yes, as long as the forms contain all of the security features pursuant to Health & Safety Code section 11162.1 et seq., including preprinted prescriber name, DEA number, state license number, and category of licensure prior to shipping to the prescriber.

**Q** As an approved security printer, can I offer prescription forms in pen-fed rolls for dot matrix printers or laser printer format for prescribers, clinics, surgery centers, group practice settings, or other outpatient facility?

**A** Yes, as long as the laser or dot matrix prescription form meets all of the requirements in Health & Safety Code section 11162.1 et seq., including preprinting the individual prescriber or list of prescribers with check boxes next to each, and all required security features, including the quantity check boxes. The computer software can generate the patient and prescription information only to print on the laser or dot matrix preprinted prescription forms. The prescriber must then sign and date the prescription. **Note:** Clinics, surgery centers, group practices or any other outpatient setting that is not licensed under Health and Safety Code section 1250, may **not** order “institution” style forms as described in the following section; institution style forms are strictly limited to licensed health care facilities defined below.

## **Prescription Forms for Licensed Health Care Facilities**

**Q** What specific “licensed health care facilities” can use the “institution” style controlled substance prescription form?

**A** The “licensed health care facility” must qualify under Article 1 (commencing with Section 1250) of Chapter 2 of Division 2 of the Health and Safety Code and be licensed by the Department of Health Services (DHS) to use the institution style form. Generally, these are inpatient, acute-care facilities such as a hospital or skilled nursing facility. In addition, the licensed health care facility must designate a single prescriber that will order the prescription forms for authorized prescribers within the facility, distribute prescription forms to those prescribers, keep a record of the forms distributed, and maintain the records for 3 years.

The institution style forms must be preprinted with “designated prescriber” then their preprinted name, category of licensure, state license number, federal controlled substance registration number, as well as, the name of the licensed health care facility, its Department of Health Services (DHS) license number, and address. The form must also contain a blank space for the actual prescriber who is writing the prescription to hand write, computer generate, or stamp in his or her name, category of licensure, license number, and federal controlled substance registration number at the time the prescription is written. **Note:** the prescription is not valid without the actual prescriber information filled in.

**Q** Can a licensed health care facility computer generate “institution” style controlled substance prescriptions to print on a shared laser or dot matrix printer within the facility?

**A** Yes, a licensed health care facility (defined above) can purchase “institution” style prescription blanks that can be used to computer generate prescriptions to print on a shared laser or dot matrix printer within the facility. These “institution” style laser or dot matrix forms must adhere to all of the provisions outlined above for “institution” style forms; including preprinting the designated prescriber’s information and incorporating the required security features pursuant to Health and Safety Code section 11162.1 et seq. However, the following provisions were added to subsection (c), as a result of Assembly Bill 30 (Richman, Statutes of 2004), specifically limited to licensed health care facilities (as defined above) only, that computer generate prescriptions using an “institution” style prescription form to print on a shared laser or dot matrix printer:

- Computer generated “institution” style laser or dot matrix prescription forms do not require the quantity check off boxes;
- The facility’s “designated prescriber” is not required to maintain a record of the prescribers to whom the institution style computer generated laser or dot matrix printer prescription forms are distributed to within the facility; and
- In addition to the patient and prescription information, the computer software can generate the actual prescriber’s name, category of licensure, DEA registration number, and license number, as well as, the date the prescription is written, to print on the “institution” style laser or dot matrix prescription form.

**Note:** these exceptions do not apply to laser or dot matrix style controlled substance prescription forms for use by a prescriber, group practice, or any outpatient setting, such as a clinic or surgery center, that are not licensed pursuant to Health and Safety Code section 1250.